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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/980,680	10/31/2001	Paul L Feldman	PU3318USw	6805

7590

06/27/2005

PETER F. CORLESS
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EXAMINER

COLEMAN, BRENDA LIBBY

ART UNIT	PAPER NUMBER
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1624

DATE MAILED: 06/27/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/980,680

Applicant(s)

FELDMAN ET AL.

Examiner

Brenda L. Coleman

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 April 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,4,5,8-14,24,25,28,29,32,34,35 and 38-41 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 4,5,8-10,13,14,25,28,29,34,35,40 and 41 is/are allowed.
- 6) ☒ Claim(s) 1,11,12,24,32,38 and 39 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims 1, 4, 5, 8-14, 24, 25, 28, 29, 32, 34, 35 and 38-41 are pending in the application.

This action is in response to applicant's amendment filed April 11, 2005. Claims 1, 4, 5, 8-10, 38 and 39 have been amended and claims 40 and 41 are newly added.

Response to Amendment

Applicant's amendments filed April 11, 2005 have been fully considered with the following effect:

1. The applicant's amendments are sufficient to overcome the 35 U.S.C. § 132, objection to the specification labeled paragraph 1, maintained in the last office action, which is hereby **withdrawn**.
2. The applicant's amendments are sufficient to overcome the 35 U.S.C. § 112, first paragraph rejection of claims 1, 10, 24, 25 and 32, labeled paragraph 2 maintained in the last office action, which is hereby **withdrawn**.
3. The applicant's amendments are sufficient to overcome the 35 U.S.C. § 102, anticipation rejection of claim 1, labeled paragraph 3 maintained in the last office action, which is hereby **withdrawn**.
4. The applicant's amendments are sufficient to overcome the 35 U.S.C. § 132, objection to the specification labeled paragraph 9, maintained in the last office action, which is hereby **withdrawn**.

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5. With regards to the 35 U.S.C. § 112, first paragraph rejection of claims 38 and 39, labeled paragraph 10 of the last office action, the applicant's arguments have been fully considered but are not found persuasive. The applicants stated that the compound recited in claims 38 and 39, attention is directed to the compounds of original claims 6 and 7 where $m = 2$ is recited, which designates the same compounds as now disclosed in claims 38 and 39. However the compounds of claims 38 and 39 are not the compounds as disclosed in claims 6 and 7 where $m = 2$, but rather the compounds of claims 38 and 39 are such that $n = 2$ not $m = 2$.

Claims 38 and 39 are rejected under 35 U.S.C. 5 1 12, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, for reasons of record and stated above.

6. The applicant's amendments are sufficient to overcome the 35 U.S.C. § 112, second paragraph rejection of claims 1, 4, 5, 9-14, 24, 25, 232, 38 and 39 labeled paragraph 11 in the last office action, which are hereby **withdrawn**.

7. The applicant's amendments are sufficient to overcome the 35 U.S.C. § 102, anticipation rejection of claims 4 and 5, labeled paragraph 12 in the last office action, which is hereby **withdrawn**.

8. The applicant's amendments are sufficient to overcome the 35 U.S.C. § 102, anticipation rejection of claims 4 and 5, labeled paragraph 13 in the last office action, which is hereby **withdrawn**.

9. The applicant's amendments are sufficient to overcome the 35 U.S.C. § 102, anticipation rejection of claims 4 and 5, labeled paragraph 14 in the last office action, which is hereby **withdrawn**.

In view of the amendment dated April 11, 2005, the following new grounds of rejection apply:

Information Disclosure Statement

10. The information disclosure statement filed November 26, 2003 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each U.S. and foreign patent; each publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. It has been placed in the application file, but the information referred to therein has not been considered. Several of the references were not available to the Examiner. It is requested that the applicants submit a copy of the references labeled 6, 7, 18-21 and 24 to complete the record.

Specification

11. The amendment filed April 11, 2005 is objected to under 35 U.S.C. 132 because it introduces new matter into the disclosure. 35 U.S.C. 132 states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows:

- a) Where R¹ is a heteroalkyl not heteroarylalkyl as described in the specification and the claims as originally filed.

Applicant is required to cancel the new matter in the reply to this Office Action.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

12. Claims 1, 24 and 32 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The definition of p where p is 1 is not specifically described in the specification with respect to the genus of Formula (I) when the definition of R⁴ and R⁵ is limited to R⁴ and R⁵ together is a double bond in the diazepine ring and R⁶ represents the group NHR⁷ wherein R⁷ is H, C₁₋₄ alkyl, benzyl, benzyl mono or disubstituted independently with halogen substituents, C₁₋₄alkylpyridyl or C₁₋₄alkylimidazolyl.

Applicant is required to cancel the new matter in the reply to this Office action.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

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13. Claims 11 and 12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The following reasons apply:

- a) Claim 11 recites the limitation "CH₂CH₂OH" in the definition of R⁷. There is insufficient antecedent basis for this limitation in the claim.
- b) Claim 12 recites the limitation "CH₂CH₂OH" in the definition of R⁷. There is insufficient antecedent basis for this limitation in the claim.

Allowable Subject Matter

14. Claims 4, 5, 8-10, 13, 14, 28, 29, 34, 35, 40 and 41 are allowed. None of the prior art of record or a search in the pertinent art area teaches the compounds and compositions of the compounds of formula (I) as claimed herein.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

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extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brenda L. Coleman whose telephone number is 571-272-0665. The examiner can normally be reached on 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson can be reached on 571-272-0661. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Brenda L. Coleman
Primary Examiner Art Unit 1624
June 23, 2005